Appendix 7:

L. Kessler e-mail to Center participants before the seminar.

Subject: OUTSIDE LEVERAGING SEMINAR/WORKSHOP - CDRH/FDA PARTICIPANTS

We are delighted you will be a participant at the October 28th Seminar on Outside Leveraging. The meeting in "120S", Piccard begins at 8:30 am sharp because we will be taping the entire program. In order to assure your early arrival, we will have coffee and tea available in Room 100W, adjacent to 120S, at 8:15 am. The back of Room 120S will be roped off for those few who arrive later.

Attached is a copy of the meeting outline and the agenda. You will also receive separately a package of case studies about US Customs, EPA, and OSHA. Please bring your case study package with you. We are sending advance copies to encourage you to read them prior to the workshop. Please note, the author granted permission for use within FDA only.

Special Note for any one who will join us during the workshop on October 29th:

If you are the lead on a project:

-Please prepare an outline of the project you are considering and submit it to Pat Spitzig by October 26th. The outline we recommend you use is the following:

Title of Project:

Presenting Problem

OL proposal

Expected costs

Anticipated Obstacles

Expected Results/Benefits to OL Partner

Expected Results/Benefits to FDA

-if you are able, please bring a lap-top computer on October 29th so we can work on projects as far as possible on that day.

-also bring background materials appropriate for planning and beginning/continuing to work on your project.

FYI: A separate note is going to the 25 OSB participants.

During the meeting the phone for emergencies is 301-594-0616, otherwise call 301-594-2812.

Encl: Agenda; Meeting Outline; Case study package (by inter-office mail)